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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,852	07/15/2003	Lincoln Muir	0942.5500001/RWE	4340

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EXAMINER	
NEGIN, RUSSELL SCOTT	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,852	MUIR ET AL.	
	Examiner	Art Unit	
	Russell S. Negin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III (claims 37-43) in the reply filed on 29 June 2006 is acknowledged.

Claims 1-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 June 2006.

Specification

The disclosure is objected to because of the following:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). See for example, Table 18. However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 because the application does not have SEQ ID NOs cited along with each sequence in the specification or the Figures. Applicants are also reminded that SEQ ID NOs are not required in the Figures per se, however, the corresponding SEQ ID NOs then are required in the brief description of the Drawings section in the specification. Applicants are also reminded that the CD-ROM sequence listing submission may replace the paper and computer readable form, sequence listing, a paper copy for the specification, statements under 37 C.F.R. § 1.821(f) and (g). Applicants are given the same response

time regarding this failure to comply as that set forth to respond to this office action. A complete response to this office action includes compliance with this sequence rule compliance requirement. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this office action.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 37, the phrase, "all known polypeptides having a specified activity," does not declare the metes and bounds of when and to whom the polypeptides in question are known.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 37-40 are rejected under 35 U.S.C. 102(e2) as being anticipated by Dumas Milne Edwards et al [USPAT 7,060,479].

Claims 37-40 state:

37. A clone collection, comprising: a plurality of clones, each clone comprising a nucleic acid sequence of interest, wherein the nucleic acid sequences of interest encode all or substantially all known polypeptides having a specified activity.

38. The clone collection of claim 37, wherein the specified activity is an enzymatic activity.

39. The clone collection of claim 38, wherein the activity is a kinase activity.

40. The clone collection of claim 37, wherein the activity is a G-protein-coupled receptor activity.

The invention of Dumas Milne Edwards et al, entitled, "Full-length human cDNAs encoding potentially secreted proteins," states as its objective on column 4, lines 48-55, "The present invention provides compositions containing a purified or isolated polynucleotide comprising, consisting of, or consisting essentially of a nucleotide sequence selected from the group consisting of: (a) the sequences of SEQ ID Nos: 1-241; (b) the sequences of clone inserts of the deposited clone pool; (c) the full coding sequences of SEQ ID Nos: 1-241; (d) the full coding sequences of the clone inserts of the deposited clone pool; (e) the sequences encoding one of the polypeptides of SEQ ID Nos: 242-482..."

Consequently, Dumas Milne Edwards et al discusses clone collections, and they further state in column 301, lines 42-45, "These receptors, which are expressed in the

brain, like the protein of the invention, are a novel family of cloned G protein-coupled receptors." G protein-coupled receptors have a finite activity.

In terms of kinases, Dumas Milne Edwards et al discusses clone collections, and they further state in column 135, lines 56-60, "The EGF receptor, and the related ErbB family of receptor tyrosine kinases, have indeed been much implicated in human cancer."

Many proteins are encoded such that it is interpreted that substantially all of certain species of enzymatic activities are encoded (i.e. G protein coupled receptors and kinases).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumas Milne Edwards et al in view of Phillips-Jones et al [Molecular and Cellular Biology, 1995, volume 15, pages 6593-6600].

Claim 41 states:

41. The clone collection of claim 37, wherein the nucleic acid sequences of interest comprise suppressible stop codons.

The invention of Dumas Milne Edwards et al, entitled, "Full-length human cDNAs encoding potentially secreted proteins," states as its objective on column 4, lines 48-55, "The present invention provides compositions containing a purified or isolated polynucleotide comprising, consisting of, or consisting essentially of a nucleotide sequence selected from the group consisting of: (a) the sequences of SEQ ID Nos: 1-241; (b) the sequences of clone inserts of the deposited clone pool; (c) the full coding sequences of SEQ ID Nos: 1-241; (d) the full coding sequences of the clone inserts of the deposited clone pool; (e) the sequences encoding one of the polypeptides of SEQ ID Nos: 242-482..."

Consequently, Dumas Milne Edwards et al discusses clone collections, and they further state in column 301, lines 42-45, "These receptors, which are expressed in the brain, like the protein of the invention, are a novel family of cloned G protein-coupled receptors." G protein-coupled receptors have a finite activity.

In terms of kinases, Dumas Milne Edwards et al discusses clone collections, and they further state in column 135, lines 56-60, "The EGF receptor, and the related ErbB family of receptor tyrosine kinases, have indeed been much implicated in human cancer."

Many proteins are encoded such that it is interpreted that substantially all of certain species of enzymatic activities are encoded (i.e. G protein coupled receptors and kinases).

However, Dumas Milne Edwards et al do not discuss stop codon suppression.

The article of Phillips-Jones et al, entitled, "Context effects on misreading and suppression at UAG codons in human cells," describes uses of clones and plasmids in generation of molecules with suppressible stop codons. (see "Plasmids used in this study" and "Immunological assays for beta-galactosidase expression," in Materials and Methods on pages 6593 and 6594).

It would have been obvious at the time of the instant invention to someone of ordinary skill in the art to modify Dumas Milne Edwards et al in view of Phillips Jones et al because Phillips Jones et al has the advantage of using sequences with suppressible stop codons as not only a means for monitoring conditional expression of genes, but also a tool for monitoring the efficiency of translation at an individual codon.

Claims 37 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumas Milne Edwards et al in view of Phillips-Jones et al as applied to claims 37 and 41 above, and further in view of Stearman et al [Science, volume 271, 1996, pages 1552-1557].

Claims 42 states:

42. The clone collection of claim 37, wherein the nucleic acid sequences of interest comprise a tag sequence and a suppressible stop codon located between the tag sequence and the encoded polypeptide.

While Dumas Milne Edwards et al in view of Phillips-Jones et al teach the use of sequences with suppressible stop codons, they do not teach the use of tag sequences in combinations with the suppressible stop codons.

In the article of Stearman et al, entitled, "A permease-oxidase complex involved in high-affinity iron uptake in yeast," Stearman et al describes uses of tags for determining the locations of certain proteins. As stated in the last paragraph of column 2 on page 1554, "We tested this hypothesis by determining the localization of the FTR1 protein, using a MYC epitope-tagged protein." The article continues to describe the use of tags and their insertions in footnote 37 on page 1557.

It would have been obvious at the time of the instant invention to someone of ordinary skill in the art to modify Dumas Milne Edwards et al in view of Phillips-Jones et al as applied to claims 37 and 41 in further view of Stearman et al because Stearman et al has the advantage of using tags to locate regions of interest which are areas of the sequence which encode desired polypeptides and stop codons.

Claims 37 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumas Milne Edwards et al in view of Senecoff et al [The Journal of Biological Chemistry, volume 261, 1986, pages 7380-7386].

43. The clone collection of claim 37, wherein the nucleic acid sequences of interest are flanked by a first and a second recombination site and the first and the second recombination sites do not recombine with each other.

The invention of Dumas Milne Edwards et al, entitled, "Full-length human cDNAs encoding potentially secreted proteins," states as its objective on column 4, lines 48-55, "The present invention provides compositions containing a purified or isolated polynucleotide comprising, consisting of, or consisting essentially of a nucleotide sequence selected from the group consisting of: (a) the sequences of SEQ ID Nos: 1-241; (b) the sequences of clone inserts of the deposited clone pool; (c) the full coding sequences of SEQ ID Nos: 1-241; (d) the full coding sequences of the clone inserts of the deposited clone pool; (e) the sequences encoding one of the polypeptides of SEQ ID Nos: 242-482..."

Consequently, Dumas Milne Edwards et al discusses clone collections, and they further state in column 301, lines 42-45, "These receptors, which are expressed in the brain, like the protein of the invention, are a novel family of cloned G protein-coupled receptors." G protein-coupled receptors have a finite activity.

In terms of kinases, Dumas Milne Edwards et al discusses clone collections, and they further state in column 135, lines 56-60, "The EGF receptor, and the related ErbB family of receptor tyrosine kinases, have indeed been much implicated in human cancer."

Many proteins are encoded such that it is interpreted that substantially all of certain species of enzymatic activities are encoded (i.e. G protein coupled receptors and kinases).

However, Dumas Milne Edwards et al do not describe the recombination sites as dictated by instant claim 43.

The study of Senecoff et al, entitled, "Directionality in FLP protein-promoted site-specific recombination is mediated by DNA-DNA pairing" illustrates on page 7381, column 1, a doubles stranded DNA sequence of interest surrounded by two recombination sites. A states in the first sentence of the abstract, "The 2u plasmid of the yeast *Saccharomyces cerevisiae* encodes a site specific recombination system consisting of plasmid-encoded FLP protein and two recombination sites on the plasmid."

It would have been obvious at the time of the instant invention for someone of ordinary skill in the art to modify Dumas Milne Edwards et al in view of Senecoff et al because Senecoff et al has the ability of using recombination sites to modify sequences for the purposes of understanding directionalities of specific proteins.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Andrew Wang, Supervisory Patent Examiner, can be reached at (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Yolanda Chadwick, whose telephone number is (571) 272-0514.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSN
14 September 2006

14 Sept 2006

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER

NOTICE TO COMPLY WITH SEQUENCE RULES	Application No.	Applicant(s)	
	10/618,852	MUIR ET AL.	
	Examiner	Art Unit	
	Russell S. Negin	1631	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reasons:

☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).

☐ 4. A copy of the "Sequence Listing in computer readable form has been submitted. However the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked up "Raw Sequence Listing".

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable. A Substitute computer readable form must be submitted as required by 37 CFR 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).

☐ 7. Other:

Applicant must provide:

☒ An initial or ☐ A substitute computer readable form copy of the Sequence Listing.

☒ An initial or ☐ A Substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same, and, where applicable, include no new matter, as required by 37 CFR 1.821(e), (f), or (g) or 1.825(b) or (d).

FOR QUESTIONS PLEASE CONTACT:

Rules Interpretation (703) 308-4216
CRF Submission Help (703) 308 4212
PatentIn software help (703) 308 6856

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